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No. _____

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IN THE

SUPREME COURT OF THE UNITED STATES

October Term, 1996

WARREN J. DOWNHOUR, D.O.,
VIRGINIA FORNEY,
RICHARD E. SHAW,
WARREN D. JACOBS,
NINO M. CAMARDESE, M.D.,
GEORGE LIERENZ,
SAM GIALLOMBARDO,
DON DAUGHERTY,
SARA PRESLEY, and
HILDA RUGGLES - - - - - - - *Petitioners*

versus

PETER SOMANI, M.D., Individually and as Director of the Ohio Department of Health, - - - - - - - - *Respondent*

PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

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August 28, 1996

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64 pp

QUESTIONS PRESENTED

Whether the Federal Medicare Act, 42 U.S.C. Sections 1395, *et seq.*, as amended, preempts Sections 4769.01 and 4769.02 of the Ohio Revised Code, as amended, which prohibit physicians from "balance billing" Medicare patients.

PARTIES TO THE PROCEEDING

All the parties to the within proceeding before the Court whose judgment is sought to be reviewed are named in the caption to this Petition as filed in this Court.

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Legislative Histories:
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Secondary Sources:
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American Medical Association, Division of Legislative Activities, Medicare: *Mandated Assignment, Health Legis. Issues,* Aug. 1987, at 28 24

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No. 95-2028

IN THE

SUPREME COURT OF THE UNITED STATES

October Term, 1995

WARREN J. DOWNHOUR, D.O., VIRGINIA FORNEY, RICHARD E. SHAW, WARREN D. JACOBS, NINO M. CAMARDESE, M.D., GEORGE LIERENZ, SAM GIALLOMBARDO, DON DAUGHERTY, SARA PRESLEY, and HILDA RUGGLES - - - - - - - *Petitioners*

v.

PETER SOMANI, M.D., individually and as Director of the Ohio Department of Health, - - - - - - - - - - *Respondents*

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

The Petitioners, WARREN J. DOWNHOUR, D.O., VIRGINIA FORNEY, RICHARD E. SHAW, WARREN D. JACOBS, NINO M. CAMARDESE, M.D., GEORGE LIERENZ, SAM GIALLOMBARDO, DON DAUGHERTY, SARA PRESLEY, and HILDA RUGGLES, respectfully pray that a Writ of Certiorari issue to review the Opinion and Judgment of the United States Court of Appeals for the

Sixth Circuit entered in this matter on June 7, 1996. This Petition is filed within ninety (90) days of the entry of the Opinion and Judgment below.

OPINIONS BELOW

The Memorandum and Order of the United States District Court for the Northern District of Ohio, Western Division, entered on October 7, 1994, is reprinted in the Appendix to this Petition at pages 17a through 28a. The Judgment of the United States District Court for the Northern District of Ohio, Western Division, entered on October 18, 1994, is reprinted in the Appendix to this Petition at page 28a. The Opinion of the United States Court of Appeals for the Sixth Circuit, entered on June 7, 1996, is reprinted in the Appendix to this Petition at pages 1a through 15a. The Judgment of the United States Court of Appeals, issued on July 1, 1996 is reprinted in the Appendix to this Petition at page 16a. The Memorandum and Order of the United States District Court for the Northern District of Ohio, Western Division, is unreported. The Opinion of the United States Court of Appeals for the Sixth Circuit is reported at 85 F.3d 261.

JURISDICTION

The Opinion and Judgment of the United States Court of Appeals for the Sixth Circuit, affirming the Memorandum and Order and Judgment of the United States District Court for the Northern District of Ohio, Western Division, were entered on June 7, 1996, and the Judgment was issued as mandate on July 1, 1996. The jurisdiction of this Honorable Court is invoked pursuant to 28 U.S.C. §1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

This case involves the following provision of the Constitution of the United States:

The Supremacy Clause, Art. VI cl.2, U.S. Const.

This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

This case also involves the following provisions of Title 42 of the United States Code, as amended:

§1395j. Establishment of supplementary medical insurance program for the aged and disabled

There is hereby established a voluntary insurance program to provide medical insurance benefits in accordance with the provisions of this part [42 U.S.C. §§ 1395j *et seq.*] for aged and disabled individuals who elect to enroll under such program, to be financed from premium payments by enrollees together with contributions from funds appropriated by the Federal Government.

§1395u. Use of carriers for administration of benefits

(a) Authority of Secretary to enter into contracts with carriers. In order to provide for the administration of the benefits under this part [42 U.S.C. §§ 1395j *et seq.*] with maximum efficiency and convenience for individuals entitled to benefits under this part [42 U.S.C. §§ 1395j *et seq.*] and for providers of services and other persons furnishing services to such individuals, and with a view to furthering coordination of the administration of the benefits under part A and under this part [42 U.S.C. §§ 1395c *et seq.* and 1395 j *et seq.*] the Secretary is authorized to enter into contracts with carriers, including carriers with which agreements under section 1816 [42 U.S.C. § 1395h] are in effect, which will perform some or all of the following functions (or, to the extent provided in such contracts, will secure performance thereof by other organizations);

and, with respect to any of the following functions which involve payments for physicians' services on a reasonable charge basis, the Secretary shall to the extent possible enter into such contracts:

(1)(A) make determinations of the rates and amounts of payments required pursuant to this part [42 U.S.C. §§ 1395j *et seq.*] to be made to providers of services and other persons on a reasonable cost or reasonable charge basis (as may be applicable);

(B) receive, disburse, and account for funds in making such payments; and

(C) make such audits of the records of providers of services as may be necessary to assure that proper payments are made under this part [42 U.S.C. §§ 1395j *et seq.*];

(b) Applicability of competitive bidding provisions; findings as to financial responsibility, etc., of carrier; contractual duties imposed by contract.

(3) Each such contract shall provide that the carrier —

(A) will take such action as may be necessary to assure that, where payment under this part [42 U.S.C. §§ 1395j *et seq.*] for a service that is on a cost basis, the cost is a reasonable cost (as determined under section 1861(v) [42 U.S.C. § 1395x(v)]);

(B) will take such action as may be necessary to assure that, where payment under this part [42 U.S.C. §§ 1395j *et seq.*] for a service is on a charge basis, such charge will be reasonable and not higher than the charge applicable, for a comparable service and under comparable circumstances, to the policyholders and subscribers of the carrier, and such payment will (except as

otherwise provided in section 1870(f) [42 U.S.C. § 1395gg(f)] be made —

(i) on the basis of an itemized bill; or

(ii) on the basis of an assignment under the terms of which (I) the reasonable charge is the full charge for the service, (II) the physician or other person furnishing such service agrees not to charge (and to refund amounts already collected) for services for which payment under this title [42 U.S.C. §§ 1395 *et seq.*] is denied under section 1154(a)(2) [42 U.S.C. §1320c-3(a)(2)] by reason of a determination under section 1154(a)(1)(B) [42 U.S.C. §1320c-3(a)(1)(B)], and (III) the physician or other person furnishing such service agrees not to charge (and to refund amounts already collected) for such service if payment may not be made therefor by reason of the provisions of paragraph (1) of section 1862(a) [42 U.S.C. §1395y(a)(1)], and if the individual to whom such service was furnished was without fault in incurring the expenses of such service, and if the Secretary's determination that payment (pursuant to such assignment) was incorrect and was made subsequent to the third year following the year in which notice of such payment was sent to such individual; . . .

* * * * *

(G) will provide to each nonparticipating physician, at the beginning of each year, a list of the physician's limiting charges established under section 1848(g)(2) [42 U.S.C. §1395w-4(g)(2)] for the year for the physicians' services mostly [most] commonly furnished by that physician;

(H) if it makes the determinations or payments with respect to physicians' services, will implement —

(i) programs to recruit and retain physicians as participating physicians in the area served by the carrier, including educational and outreach activities and the use of professional relations personnel to handle billing and other problems relating to payment of claims of participating physicians; and

(ii) programs to familiarize beneficiaries with the participating physician program and to assist such beneficiaries in locating participating physicians. . . .

§1395w-4. Payment for physicians' services

(a) *Payment based on fee schedule.* (1) In general. Effective for all physicians' services (as defined in subsection (j)(3)) furnished under this part during a year (beginning with 1992) for which payment is otherwise made on the basis of a reasonable charge or on the basis of a fee schedule under section 1834(b) [42 U.S.C. §1395m(b)], payment under this part [42 U.S.C. §§ 1395j *et seq.*] shall instead be based on the lesser of —

(A) the actual charge for the service, or

(B) subject to the succeeding provisions of this subsection, the amount determined under the fee schedule established under subsection (b) for services furnished during that year (in this subsection referred to as the "fee schedule amount").

(g) *Limitation on beneficiary liability.* (1) Limitation on actual charges for unassigned claims. If a nonparticipating physician knowingly and willfully bills on a repeated basis for physicians' service (furnished with respect to an individual enrolled under this part [42 U.S.C. §§ 1395j *et seq.*] on or after January 1, 1991)

an actual charge in *excess of the limiting charge* described in paragraph (2) and for which payment is not made on an assignment-related basis under this part [42 U.S.C. §§ 1395j *et seq.*], the Secretary may apply sanctions against such physician in accordance with section 1842(j)(2) [42 U.S.C. §1395u(j)(2)].

(2) "Limiting charge" defined. (A) For 1991. For physicians' service of a physician furnished during 1991, other than radiologist services subject to section 1834(b) [42 U.S.C. §1395m(b)], the "limiting charge" shall be the same percentage (or, if less, 25 percent) above the recognized payment amount under this part [42 U.S.C. §§ 1395j *et seq.*] with respect to the physician (as a nonparticipating physician) as the percentage by which —

(i) the maximum allowable actual charge (as determined under section 1842(j)(1)(C)] as of December 31, 1990, or, if less, the maximum actual charge otherwise permitted for the service under this part [42 U.S.C. §§ 1395j *et seq.*] as of such date) for the service of the physician, exceeds

(ii) the recognized payment amount for the service of the physician (as a nonparticipating physician) as of such date.

* * * * *

(C) After 1992. For physicians' services furnished in a year after 1992, the "limiting charge" shall be 115 percent of the recognized payment amount under this part [42 U.S.C. §§ 1395j *et seq.*] for nonparticipating physicians.

(D) Recognized payment amount. In this section, the term "recognized payment amount" means, for services furnished on or after January 1, 1992, the fee schedule amount determined under subsection (a), and, for services furnished during 1991,

the applicable percentage (as defined in section 1842(b)(4)(A)(iv) [42 U.S.C. §1395u(b)(4)(A)(iv)]) of the prevailing charge (or fee schedule amount) for nonparticipating physicians for that year.

This case also involves the following provisions of the Ohio Revised Code, as amended:

Sec. 4769.01. As used in this chapter:

(A) "Medicare" means the program established by *Title XVIII* of the "Social Security Act," 49 Stat. 620 (1935), 42 U.S.C.A. 301, as amended.

(B) "Balance billing" means charging or collecting an amount in excess of the medicare reimbursement rate for medicare-covered services or supplies provided to a Medicare beneficiary, except when Medicare is the secondary insurer. When Medicare is the secondary insurer, the health care practitioner may pursue full reimbursement under the terms and conditions of the primary coverage and, if applicable, the charge allowed under the terms and conditions of the appropriate provider contract, from the primary insurer, but the Medicare beneficiary cannot be balance billed above the Medicare reimbursement rate for a Medicare-covered service or supply. "Balance billing" does not include charging or collecting deductibles or coinsurance required by the program.

(C) "Health Care Practitioner" Means All of the Following:

* * * * *

(6) A physician [[as defined in section 4730.01]] authorized under chapter 4731. of the Revised Code to practice medicine and surgery, osteopathic medicine and surgery, or podiatry;

* * * * *

Sec. 4769.02. No health care practitioner, and no person that employs any health care practitioner, shall balance bill any supplies or services provided to a medicare beneficiary.

STATEMENT OF THE CASE

I. How the Federal Questions Are Presented.

The Federal Constitutional and statutory questions involved in this case were initially presented in the Petitioners' Verified Complaint for Declaratory Judgment and Injunctive Relief filed pursuant to 28 U.S.C. §1331, 28 U.S.C. §2201 and Rule 57 of the Federal Rules of Civil Procedure on December 6, 1993 in the United States District Court for the Northern District of Ohio, Western Division. The Verified Complaint for Declaratory Judgment and Injunctive Relief states, *inter alia*, as follows:

> 1. This is a civil action arising under the Constitution and laws of the United States, specifically Article VI, clause 2, and Article I, Section 10, and the First, Fourth, Fifth, Ninth and Fourteenth Amendments to the Constitution of the United States and the Medicare Act, Title 42 U.S.C. Section 1395 *et seq.*, and is brought pursuant to Title 28 U.S.C. Sections 1331, 1361 and 1651, and Title 42 U.S.C. Section 1983. Plaintiffs seek a declaratory judgment that Sections 4769.01 and 4769.02 of an Act Amending the Revised Code of Ohio, which prohibit any health care practitioner from balance billing for any supplies or services to a Medicare beneficiary, be declared unconstitutional. Plaintiffs seek temporary and permanent injunctive relief, enjoining the Defendants, PETER SOMANI, M.D., individually, and as Director of THE OHIO DEPARTMENT OF HEALTH, and THE OHIO DEPARTMENT OF HEALTH, from enforcing the aforesaid Sections 4769.01 and 4769.02 of an Act Amending the Revised Code of Ohio. This Court may grant such relief in this action under authority of Title 28 U.S.C. Sections 1361 and 2201 and Rules 57 and 65 of the Federal Rules of Civil Procedure.
>
> * * * * *
>
> 45. That Sections 4769.01 and 4769.02 of an Act Amending the Revised Code of Ohio prohibit the Plain-

> tiff physicians from balance billing, a practice which is specifically recognized and required in the Medicare Act, 42 U.S.C. Sections 1395 *et seq.*, and which practice the Congress of the United States specifically reaffirmed when it rejected an amendment to ban balance billing in the recent passage of the Omnibus Budget Reconciliation Act of 1993, which was signed into law on August 10, 1993, and, therefore, the said Sections 4769.01 and 4769.02 of an Act Amending the Revised Code of Ohio, banning balance billing is violative of the Medicare Act, 42 U.S.C. Section 1395 *et seq.*, and, consequently, the Supremacy Clause of Article VI, Clause 2, of the Constitution of the United States.

(Rec.Doc. 1: Complaint).

Petitioners plead that no adequate remedy at law existed and prayed for the relevant declaratory and injunctive relief. (Rec.Doc. 1: Complaint).

II. Statement of Facts

In 1965, the United States Congress established the Medicare program by enacting Title XVIII of the Social Security Act. The Medicare program consists of two parts: Part A, Hospital Insurance Benefits for the Aged and Disabled, now codified at 42 U.S.C. §§ 1395c — 1395i-4; and Part B, Supplementary Medical Insurance Benefits for the Aged and Disabled, 42 U.S.C. §§ 1395j — 1395w-4. Part B of the Medicare program covers certain medical services, including physicians' services, under a so-called voluntary program of supplementary medical insurance benefits. Under Part B of the Medicare program, payment for physicians' services may be made either (1) to the patient on the basis of an itemized bill from the physician, or (2) directly to the physician pursuant to an assignment agreement. 42 U.S.C. §1395u(b)(3). Under Part B of the Medicare program, each year a physician may choose to be either a "participating" physician or "non-participating" physician. 42 U.S.C. §1395u(b)(4).

"Participating" physicians are those who voluntarily choose to enter into agreements with the Secretary of the United States Department of Health and Human Services ("the Secretary") to accept assignment on all services provided to Medicare patients by billing Medicare directly for the services rendered. 42 U.S.C. §1395u(h). By accepting assignment and entering into participation agreements, "participating" physicians also agree to accept the amount specified by the Secretary for the particular service as full payment for services rendered, with Medicare paying eighty percent (80%) of what the Secretary has determined to be the approved rate pursuant to 42 U.S.C. §1395w-4 and with the patient being responsible for the remaining required copayment of twenty percent (20%). 42 U.S.C. §1395u(b)(3)(ii). By accepting assignment and entering into a participation agreement, a "participating" physician agrees to accept the resulting one-hundred percent (100%) of the Medicare-approved rate as full payment for the services rendered and may not bill the patient for any additional amounts. 42 U.S.C. §1395l(a)(1).

In contrast, "non-participating" physicians choose not to enter into participation agreements with the Secretary. "Non-participating" physicians are not required to accept assignment for services rendered to Medicare patients, with certain narrow and specified statutory exceptions, but may choose to do so on a case-by-case basis. A "non-participating" who chooses not to accept assignment may bill the Medicare patient directly on the basis of an itemized bill. Under the federal Medicare statute, the "non-participating" physician, like a "participating" physician, receives eighty percent (80%) of the Medicare-approved charge from Medicare and collects the remaining twenty percent (20%) copayment from the patient. However, the Medicare Act, 42 U.S.C. §§1395 *et seq.*, and specifically 42 U.S.C. §§1395u(b), 1395(1) and 1395w- 4(g), as amended, grant "non-participating" physicians the right to balance bill for

services which they render to Medicare patients up to the "limiting charge" set forth in 42 U.S.C. §1395w-4(g)(1) and (2). Under 42 U.S.C. §1395w-4(g)(1) and (2), the "limiting charge" was twenty-five percent (25%) of the Medicare-approved rate for 1992, and fifteen percent (15%) of the Medicare-approved rate for 1993 and beyond.

On or about January 9, 1993, the Governor of Ohio signed into law Sections 4769.01 and 4769.02 of "An Act Amending the Revised Code of Ohio," which prohibited health care providers, including the Petitioners, from balance billing those Medicare patients whose family incomes were less than six-hundred percent (600%) of the federal poverty guidelines. Sections 4769.03 through 4769.10 of the Ohio Revised Code further provided for civil penalties to be imposed by the Respondent, the Director of the Ohio Department of Health, and civil actions by the Ohio Attorney General for repayments of amounts collected by physicians in violation of the balance billing law, with interest.

On or about August 25, 1995, while this case was on appeal before the United States Court of Appeals for the Sixth Circuit, the Governor of Ohio signed into law certain amendments to Sections 4769.01 and 4769.02 of the Ohio Revised Code which eliminated the "family income" requirement of the previous statutes, thereby imposing the Ohio balancing billing ban to services provided to all Medicare patients, regardless of income.

III. Proceedings Below

On December 6, 1993, the Petitioners, "non-participating" Ohio physicians and their patients, filed this action against the Ohio Department of Health (ODH) seeking a declaratory judgment and injunctive relief prohibiting the enforcement of Sections 4769.01 and 4769.02 of the Ohio Revised Code prohibiting physicians from "balance billing" Medicare-enrolled patients whose "family incomes" are at or below six-hundred percent (600%) of the poverty level

on the grounds, *inter alia,* that Sections 4769.01 and 4769.02 are preempted by the Medicare Act, 42 U.S.C. §§1395, *et seq.* On December 30, 1993, ODH filed a motion to dismiss, asserting Eleventh Amendment immunity. On January 14, 1994, the Petitioners filed and served their Verified First Amended and Substituted Complaint for Declaratory Judgment and Injunctive Relief ("Amended Complaint") naming as a Defendant the Respondent, Peter Somani, M.D., individually, and as Director of the Ohio Department of Health. Also on January 14, 1994, the Petitioners filed and served their Memorandum in Opposition to the Motion to Dismiss, relying upon the Amended Complaint. Thereinafter, ODH moved to strike the Amended Complaint or, in the alternative, to dismiss, again relying upon Eleventh Amendment immunity, and arguing that the Amended Complaint was improperly filed without leave. On February 25, 1994, Petitioners filed, *inter alia,* a Motion for Leave to File the Amended Complaint and a Motion for Summary Judgment.

In a Memorandum and Order dated March 23, 1994, the United States District Court for the Northern District of Ohio, Western Division, granted Petitioners leave to file the Amended Complaint *nunc pro tunc,* granted ODH's Motion to Dismiss ODH as a party- defendant on grounds of Eleventh Amendment immunity, denied Petitioners' Motion for Summary Judgment with leave to refile the motion, and denied all other pending motions as moot.

Thereafter, the Respondent filed a Motion to Dismiss, and both the Petitioners and the Respondent filed cross-motions for summary judgment. On October 7, 1994, the District Court issued its Memorandum and Order granting the Respondent's Motion for Summary Judgment and denying the Petitioners' Motion for Summary Judgment, holding, *inter alia,* that Sections 4769.01 and 4769.02 of the Ohio Revised Code are not preempted by the Medicare Act,

42 U.S.C. §§1395, *et seq.*, as amended. October 7, 1994, Memorandum and Order, Appendix pps. 17a-27a.

On October 18, 1994, the United States District Court entered its Judgment granting Respondent's Motion for Summary Judgment, denying Petitioners' Motion for Summary Judgment, and overruling all other pending motions as moot. October 18, 1994 Judgment, Appendix p. 28a.

The Petitioners appealed to the United States Court of Appeals for the Sixth Circuit. Oral argument was held on January 26, 1996. On June 7, 1996, the United States Court of Appeals for the Sixth Circuit filed an Opinion and Judgment affirming the Judgment of the United States District Court for the Northern District of Ohio, Western Division, holding that Ohio's ban on balance billing of Medicare patients was not preempted by the Medicare Act, 42 U.S.C. §§1395, *et seq.* June 7, 1996 Opinion, Appendix p. 1a.

REASONS FOR GRANTING THE WRIT

I. Sections 4769.01 and 4769.02 of the Ohio Revised Code, as Amended, Are Preempted by the Medicare Act, 42 U.S.C. §§1395, *et seq.*, and Are Therefore Violative of the Supremacy Clause, Article VI, Clause 2, of the United States Constitution.

Under the Supremacy Clause of the Federal Constitution, Article VI, Clause 2, state laws which "interfere with, or are contrary to, the laws of Congress, made in pursuance of the Constitution," are invalid. *Gibbons* v. *Ogden,* 9 Wheat. 1, 211, 6 L.Ed. 23, 73 (1824) (Marshall, C.J.). The three ways in which federal law may preempt state law are well-established, and preemption fundamentally is a question of Congressional intent. *Schneidewind* v. *ANR Pipeline Co.,* 485 U.S. 293, 299 (1988). In order to discern Congressional intent, courts examine the explicit statutory language as well as the overall structure and purpose of the federal statutory scheme. *FMC Corp.* v. *Holliday,* 498 U.S. 52, 56-57 (1990).

First, Congress' intent to supplant or preempt state authority in a particular field may be expressed explicitly in the terms of the statute. *Jones* v. *Rath Packing Co.*, 430 U.S. 519, 525 (1977). Second, absent express preemptive language, Congress' intent to supersede state law in a given area may nonetheless be implicit if a scheme of federal regulation is "so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it," if "the Act of Congress . . . touch[es] a field in which the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject," or if the goals "sought to be obtained" and the "obligations imposed" reveal a purpose to preclude state authority. *Pacific Gas & Electric Co.* v. *State Energy Resources Conservation and Development Commission*, 461 U.S. 190, 203-204 (1983). Federal preemption may be presumed when the federal legislation is "sufficiently comprehensive to make reasonable the inference that Congress left no room for supplementary state regulation." *International Paper Co.* v. *Ouellette*, 479 U.S. 481, 491 (1987).

Finally, even when Congress has not chosen to occupy a particular field, preemption may occur to the extent that state and federal law actually conflict. *Ray* v. *Atlantic Richfield Co.*, 435 U.S. 151, 158 (1988). Such a conflict arises when "compliance with both federal and state regulations is a physical impossibility," *Florida Lime & Avocado Growers, Inc.* v. *Paul*, 373 U.S. 132, 142-143 (1963), or when a state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Hines* v. *Davidowitz*, 312 U.S. 52, 67 (1941). Further, a federal regulatory agency may exercise its delegated authority to preempt state law, and federal regulations have no less preemptive effect than federal statutes. *Fidelity Federal Savings & Loan Ass'n* v. *De La Cuesta*, 458 U.S. 141, 153-154 (1982). In addition, a state

law whose central purpose is to regulate matters that Congress intended a federal agency to regulate is preempted. *Schneidewind* v. *ANR Pipeline Co.*, 485 U.S. 293, 308-309 (1988).

In *Fidelity Federal Savings & Loan Ass'n* v. *De La Cuesta*, 458 U.S. 141 (1982), this Honorable Court held that the Federal Home Loan Bank Board's regulation permitting federally chartered savings and loan associations to exercise a due-on-sale clause of a mortgage barred the application of a contrary state doctrine. In *De La Cuesta*, the Federal Home Loan Bank Board ("the Board") issued a federal regulation permitting federal savings and loan associations to use "due-on-sale" clauses in their mortgage contracts. In contrast, California Civil Code § 711, as interpreted by the California Supreme Court, prohibited the exercise of a due-on-sale clause in a mortgage contract unless the lender could demonstrate that enforcement of the clause was reasonably necessary to protect against impairment to its security interest or the risk of default.

This Honorable Court held that the Board's federal regulation permitting, but not requiring, federally chartered savings and loan associations to exercise due-on-sale clauses in mortgage contracts barred the application of California Civil Code, §711. This Honorable Court observed:

> As even the Court of Appeal recognized, the Board's intent to pre-empt the Wellenkamp doctrine is ambiguous. The due-on-sale regulation plainly provides that a federal savings and loan "continues to have the power" to include a due-on-sale clause in a loan instrument and to enforce that clause "at its option." 12 CFR §545.8-3(f) (1982). The California courts, in contrast, have limited a federal association's right to exercise a due-on-sale provision to those cases where the lender can demonstrate that the transfer has impaired its security.

> The conflict does not evaporate because the Board's regulation simply permits, but does not compel, federal savings and loans to include due-on-sale clauses in their contracts and to enforce those provisions when the security property is transferred. The Board consciously has chosen not to mandate use of due-on-sale clauses "because [it] desires to afford associations the flexibility to accommodate special situations and circumstances." 12 CFR §556.9(f)(1) (1982) [footnote omitted]. Although compliance with both §545.8-3(f) and the Wellenkamp rule may not be a "physical impossibility", Florida Lime & Avocado Growers, Inc. v. Paul, 373 U.S., at 142-143, 83 S.Ct., at 1217, the California courts have forbidden a federal savings and loan to enforce a due-on-sale clause "at its option" and have deprived the lender of the "flexibility" given it by the Board.
>
> * * * * *
>
> By further limiting the availability of an option the Board considers essential to the economic soundness of the thrift industry, the State has created "an obstacle to the accomplishment and execution of the full purposes and objectives" of the due-on-sale regulation [Citations omitted].

De La Cuesta, 458 U.S. at 154-156.

Most recently, in *Barnett Bank of Marion County, N.A.* v. *Nelson,* ___ U.S. ___, 116 S.Ct. 1103 (1996), this Honorable Court unanimously reaffirmed the sound principles of *De La Cuesta* to hold a Florida statute preempted by federal statute. In *Barnett Bank,* a national bank brought an action for declaratory and injunctive relief challenging on preemption grounds a Florida statute which prohibited banks from selling insurance in towns having a population of less than five-thousand (5,000). In 1916, Congress had enacted a federal statute which stated that certain national banks "may" sell insurance in places with a population of not more than five-thousand (5,000). In 1974,

however, the State of Florida enacted a statute which prohibited certain banks from selling insurance. The Petitioners maintained, *inter alia*, that the 1916 federal statute preempted the Florida statute and that the special insurance-related anti-preemption rule of the McCarran-Ferguson Act did not salvage the Florida statute. The District Court and the United States Court of Appeals for the Eleventh Circuit disagreed, holding that the Florida statute was not preempted by federal law. This Honorable Court unanimously reversed, holding that the Florida statute was preempted by the 1916 federal statute and was not saved by the special insurance-related anti-preemption rule of the McCarran-Ferguson Act, holding, *inter alia*, as follows:

> The Federal Statute before us, as in *Franklin Nat. Bank [v. New York*, 347 U.S. 373 (1954)], explicitly grants a national bank an authorization, permission, or power. And, as in *Franklin Nat. Bank*, it contains no "indication" that Congress intended to subject that power to local restriction. Thus, the Court's discussion in *Franklin Nat. Bank*, the holding of that case, and the other precedent we have cited above, strongly argue for a similar interpretation here — a broad interpretation of the word "may" that does not condition federal permission upon that of the State.

Barnett Bank, ___ U.S. ___ at ____, 116 S.Ct. at 1109-1110.

In the context of the federal Medicare program, lower federal courts have followed the statutory construction principles and reasoning of *De La Cuesta* and *Barnett Bank* to hold state intrusions upon federal statutory billing options of health care providers invalid under the Medicare Act and the Supremacy Clause of the United States Constitution. In *New York City Health and Hospitals* v. *Perales*, 954 F.2d 854 (2nd Cir. 1992), *cert. denied*, ___ U.S. ___, 113 S.Ct. 461, 121 L.Ed.2d 369 (1992), health care providers brought an action against the Commissioner of Social

Services of the State of New York challenging a New York regulation which limited the state's responsibility for Medicare Part B cost-sharing coverage for patients who were "dual eligibles", or Medicare beneficiaries who also qualified for Medicaid assistance. The Plaintiffs argued that the New York regulation violated the Medicare Act because it effectively precluded them from collecting their full reasonable charges as determined under Medicare. The United States District Court dismissed the complaint, but the Second Circuit reversed, holding that the New York regulation violated both the Medicare Act and the federal Medicaid Act. The Second Circuit first held that providers who furnish medical care to Medicare-eligible patients have the right to collect 100% of their reasonable costs or charges. *New York City Health and Hospitals,* 954 F.2d at 858. The Second Circuit then went on to hold as follows:

> As Plaintiffs-Appellants note, there is nowhere articulated in the Medicare Act or regulations an exception for dual eligible or QMBs or any limitation on providers' express statutory right to recover their full reasonable costs or charges. Despite this right, the Regulation at issue limits New York State's cost-sharing contribution to the Medicaid rate, an amount that is less than a provider's reasonable costs or charges, and prohibits providers from collecting anything form the patients themselves. In other words, the Regulation precludes providers who serve dual eligibles and QMBs pursuant to a buy-in arrangement from collecting more than 80% of their reasonable costs or charges in the overwhelming majority of cases.
>
> The Regulation therefore appears, on its face, to violate the Medicare Act. The Secretary has nevertheless approved it, on the ground, accepted by the district court, that dual eligibles and QMBs are "primarily Medicaid patients" since they received Part B Medicare coverage only because the State has enrolled them due to their status as Medicaid patients or poor

> individuals. In the Secretary's understanding, then, providers supplying care to such individuals are therefore not entitled to receive their reasonable costs or charges. We do not accept this reasoning. The Medicare Act on its face entitled providers to collect their reasonable costs or charges, an entitlement which is frustrated by the Regulation.

New York City Health and Hospitals, 954 F.2d at 858.

The Second Circuit also specifically examined the language and purpose of the Medicare Act, finding that the permissive language of the Medicare statute ("may") created a federal entitlement of the health care provider to receive his or her "reasonable charge" for services rendered. The Second Circuit observed:

> Under the Medicare Act, a provider of services to a Medicare-eligible individual pursuant to the Medicare Act receives from the federal government, after deduction of the annual deductible, 80% of the reasonable costs or charges for such services. To collect the remaining portion of the provider's compensation, the provider **"may charge** such [Medicare-eligible] individual or other person (i) the amount of any deduction. . . and (ii) an amount equal to 20 per centum of the reasonable charges for such items and services. . . for which payment is made under part B. . . ." 42 U.S.C. § 1395cc(a)(2)(A). In other words, providers who furnish medical care to Medicare-eligible patients **have the right** to collect 100% of their reasonable costs or charges [Citations omitted].

New York City Health and Hospitals, 954 F.2d at 858 (Emphasis added.)

At bottom, the statutory language quoted in *New York City Health and Hospitals*, by use of the term "may" rather than "shall", created a federal statutory option for providers but did not **require** providers to exercise this option. Nevertheless, the Second Circuit concluded that providers

possessed a federal statutory right to collect their full reasonable charges from a beneficiary and that the state regulation at issue facially frustrated that federal statutory right and was therefore violative of the Supremacy Clause of the Constitution of the United States. Other federal cases from various federal circuits are in accord with the reasoning and holding in *New York City Health and Hospitals*. *See, Rehabilitation Ass'n of Virginia, Inc.* v. *Kozlowski*, 838 F. Supp. 243, 249-250 (E.D. Va. 1993), *aff'd* 1994 WL 677413 (4th Cir. Dec. 5, 1994); *Pennsylvania Medical Soc.* v. *Snider*, 29 F.3d 886 (3rd Cir. 1994); *Haynes Ambulance Service, Inc.* v. *State of Ala.*, 36 F.3d 1074 (11th Cir. 1994).

When this Honorable Court examines the language, structure, and history of the Medicare Act in light of the principles set forth in *De La Cuesta*, *Barnett Bank*, and *New York City Health and Hospitals*, it is manifest that Ohio's ban on balance billing infringes upon the long-established federal statutory option, indeed, right, of health care providers to balance bill their patients up to the federally-established "limiting charge" set forth in 42 U.S.C. §1395w-4, and that the lower courts erred in holding to the contrary.

Pursuant to 42 U.S.C. §1395u, Congress has delegated to the Secretary of the United States Department of Health and Human Services the authority to enter into contracts with local insurance carriers to administer the federal Medicare program in accordance with the governing federal statutes and regulations. The Secretary, through the Health Care Financing Administration, has exercised this delegated authority by entering into contracts with carriers for administration of the federal program in every state and territory of the United States. The federal Medicare carriers (and other specified entities) are empowered, *inter alia*, to "make determinations of the rates and amounts of payments required pursuant to this part", (42 U.S.C. §§1395j,

et seq.), 42 U.S.C. §1395u(a)(1)(A), to "receive, disburse and account for funds in making such payments", 42 U.S.C. §1395u(a)(1)(B); and, to "make such audits of the records of providers of services as may be necessary to assure that proper payments are made under this part (42 U.S.C. §§1395j, *et seq.)*. 42 U.S.C. §1395u(a)(1)(C).

Most importantly, within 42 U.S.C. §1395u, Congress specifically granted physicians treating Medicare-enrolled patients the two options and specifically instructed the Secretary to require Medicare carriers to recognize the options of either billing the patient only the amount reimbursable by Medicare "on the basis of an assignment" 42 U.S.C. §1395u(b)(3)(ii), or billing the patient "on the basis of an itemized bill", 42 U.S.C. §1395u(b)(3)(i). If a physician performs a health care service and submits a claim to Medicare "on the basis of an itemized bill", the physician may charge and collect from the patient an amount in excess of the amount actually reimbursable by Medicare. 42 U.S.C. §1395w-4(g)(2)(C). If a physician accepts an "assignment" under 42 U.S.C. §1395u(b)(3)(ii), the physician may only collect, directly from Medicare, the amount reimbursable by Medicare. The former practice is commonly referred to as "balance billing" and, with respect to non-participating physicians such as the physicians herein, such practice has always been an express statutory option for physicians since the inception of the vast federal program in 1965. Moreover, each time Congress has considered the option of eliminating the right of non-participating physicians to "balance bill" by requiring assignment for all health care services rendered to patients enrolled in Medicare, it has consciously chosen to keep the statutory right intact because to do otherwise would depart from longstanding federal policy. Because of the unknown effects of such legislation on federal Medicare beneficiaries in terms of access to care and freedom of choice of physicians, two overarching goals of the federal Medicare pro-

gram, the "balance billing" option was put into place in order to give Medicare-enrolled patients the same choices they would have if privately insured. *See, U.S. President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, 1 Securing Access to Health Care,* 146 (1983).

Congress has considered various proposals to reform health care financing and delivery. *See generally, Proposals to Modify Medicare's Physician Payment System: Hearings Before the Senate Subcommittee on Health of the Committee on Finance,* 99th Cong., 2d Sess. (1986). In 1984, Congress specifically rejected a proposal mandating physicians to accept assignment, and, therefore, not "balance bill", for services provided to all Medicare-enrolled patients. H.R. 4170, 98th Cong., 2d Sess. 1006 (1984). In rejecting the proposal, numerous reasons were given. Importantly, Senator Edward Kennedy, one of the prime architects of the federal Medicare program when it was enacted in 1965, commented that "the fundamental compromise that permitted passage of Medicare in 1965. . . was the bargain. . . that physicians would still be able to pursue additional private charges from their patients, **free of government restraint**." 130 Cong. Rec. 55498 (daily ed. May 9, 1984) (emphasis added). In addition to relying on the fundamental assumption behind the Medicare program at the time of its inception, some members of Congress directly expressed their concerns about the potential adverse effects of mandatory assignment, and thus, an outright prohibition on "balance billing", and were unwilling to take the risk involved in passing the amendment. Representative Steinhold remarked:

> I am unalterably opposed to the mandatory assignment provisions at this time . . . [they] have not been subject to congressional hearings and review. We have no idea what kind of impact they could have on the Medicare program. . . . Until we can be more informed

> about these effects, we should not approve the mandatory assignment provisions.

130 Cong. Rec. H2799 (daily ed. Apr. 12, 1984).

Additionally, Representative Roberts of Kansas stated, "[w]hat is wrong with this simple approach is that no one here knows how many physicians would continue to treat our Medicare patients. . . . This proposal puts another obstacle on retaining access to health care in our rural areas." 130 Cong. Rec. H2800 (daily ed. Apr. 12, 1984).

Furthermore, in developing the fiscal year 1988 budget reconciliation package, the House Ways and Means Committee expressly rejected a mandatory assignment amendment which would have prohibited "balance billing" of Medicare patients by a 30 to 5 vote. American Medical Association, Division of Legislative Activities, *Medicare: Mandated Assignment, Health Legis. Issues*, Aug. 1987, at 28. As of August 6, 1987, 326 members of the House of Representatives and 46 Senators had co-sponsored concurrent resolutions (S. Cong. Res. 15 and H. Con. Res. 20) that directly state opposition to mandatory Medicare assignment and its concomitant prohibition on "balance billing" of Medicare patients for health care services. *Id.* Additionally, when Congress recognized the need of the federal Medicare program to prohibit "balance billing" or require payment only on the basis of an assignment with respect to specific items or services provided to Medicare beneficiaries, it has specifically done so. *See, e.g.*, 42 U.S.C. §13951(h)(5)(o) ("[a] person may not bill for clinical diagnostic laboratory test, including a test performed in a physician's office but excluding a test performed by a rural health clinic, other than on an assignment-related basis"); 42 U.S.C. §1395l(p) (payment to nurse midwives, clinical social workers, and for qualified psychologists services only on an assignment-related basis); 42 U.S.C.§13951(r) (payment for services relating to a nurse practitioner or clini-

cal nurse specialist services provided in rural area may be made only on an assignment-related basis).

In addition to rejecting a prohibition on "balance billing" because of its direct opposition to what prompted the passage of Medicare and the potentially adverse effect on program beneficiaries of removing the "balance billing" option from the Medicare Act, in the late 1980's and early 1990's, Congress embarked on comprehensive and complicated physician payment reform under Medicare. Rather than eliminating the "balance billing" option for physicians treating Medicare patients, Congress designed and implemented the "participating physician" program making assignment more attractive by providing incentives to physicians willing to enter into a "participation agreements" for twelve months, with the physicians voluntarily agreeing not to "balance bill" any Medicare patients during that twelve-month period. *See,* 42 U.S.C. §1395u(h).

In 1989, after over five (5) years of Congressionally-mandated studies by the Health Care Financing Administration, Congress also radically altered the payment scheme of Medicare Part B. As part of the "Omnibus Budget Reconciliation Act of 1989", Pub.L. 101-239 (December 19, 1989) ("OBRA '89"), Congress authorized the Secretary to establish a physician fee schedule which based Medicare payment rates to physicians on, *inter alia*, the "relative value" of the particular service rendered by the physician. On November 5, 1990, Congress enacted Public Law 101-508, the "Omnibus Budget Reconciliation Act of 1990" ("OBRA '90"), which contained several modifications and clarifications to the Public Law 101-239 provisions establishing the physician fee schedule. On November 25, 1991, the Health Care Financing Administration published the final rule establishing the Medicare fee schedule to take effect January 1, 1992. *See,* 56 *Federal Register* 59526. The Health Care Financing Administration now yearly "up-

dates" and adjusts the fee schedule and publishes a new fee schedule every year pursuant to its exclusive statutory authority over such Medicare payment issues. These changes in the method of physician payment under Medicare Part B setting forth the complex statutory framework for the development and implementation of the Medicare fee schedule are currently codified at 42 U.S.C. §1395w-4.

Physicians' fees under the fee schedule are set using such factors as "the adjusted historical payment basis" for the particular service, 42 U.S.C. §1395w-4(a)(2)(D)(i), the "relative value" of the particular physician's service, 42 U.S.C. §1395w-4(c), a "conversion factor" assigned to the particular physician's services, 42 U.S.C. §1395w-4(d), and a "geographic adjustment factor" to reflect variations in medical practice costs in various areas throughout the country. 42 U.S.C. §1394w-4(e). 42 U.S.C. §1395w-4(g) limits the amount which "non-participating" physicians may charge Medicare beneficiaries by establishing what is commonly referred to as the "limiting charge." Conspicuously, 42 U.S.C. §1395w-4(g) expressly authorizes, but does not require, physicians to charge their Medicare patients up to the "limiting charge" set forth in the federal statutory scheme. "Non-participating" physicians who knowingly and willfully exceed the "limiting charge" provisions of the statute when claims are filed with Medicare are subject to severe sanctions. 42 U.S.C. §1395u(j)(2)(B); 42 U.S.C. §1320a-7a(a). Thus, the Medicare Act read as a whole, and specifically 42 U.S.C. §§1395u(b), 1395l and 1395w-4, as amended, historically has granted, and continues to grant, "non-participating" physicians the express right to balance bill for services which they render to Medicare patients up to the "limiting charge" established by the federal statutory formula.

As late as 1993, a United States Senate Amendment would have eliminated balance billing altogether, as Ohio

has done here. However, a Conference Committee considering that proposal as part of the Omnibus Budget Reconciliation Act of 1993 rejected it outright. *See* H.R. Rep. 103-213 (August 4, 1993) at 771.

When this Honorable Court considers that Congress actively considered prohibitions on balance billing in its vast federal Medicare program and categorically rejected such prohibitions as conflicting with the federal policy underlying the Medicare program, including the overarching goal of assuring Medicare-enrolled patients access to care, it is manifest that it left no room for the states to interfere with the detailed federal scheme to the detriment of Medicare-enrolled patients' access to the physician of their choice and to physicians who treat Medicare patients. Additionally, Congress deliberately embarked on a comprehensive federal policy of physician payment reform which involved over five years of study, millions of dollars, and direct Congressional and federal agency oversight in order to assure that the federal policy goals of the Medicare program were not undermined. Indeed, in mandating that the Health Care Financing Administration develop a fee schedule Congress explicitly instructed the federal agency to take local conditions into account in implementing physician payment reform under Medicare, rather than allowing for a patchwork of state-by-state regulation of Medicare fees and charges. *See,* U.S.C. §1395w-4(e) (regarding "geographic adjustment factors" under physician fee schedule).

As in *De La Cuesta,* those federal actors having exclusive oversight over the Medicare program intentionally left the option of balance billing in place to ensure flexibility for physicians and access by Medicare patients. As in *Ouellette,* Congress entrusted exclusively to a federal administrative agency, specifically the Health Care Financing Administration, the exclusive oversight of physician payment reform under Medicare. As in *Barnett Bank* and

New York City Health and Hospitals, Congress has statutorily granted "non-participating" physicians the express permission, indeed, the right, to balance bill their Medicare patients up to the "limiting charge" established by federal statute, and the federal statute does not condition federal permission upon that of the State of Ohio. By directly interfering with the fundamental policies and goals of the federal Medicare program, the Ohio statute is in conflict with the workings of a complex, exclusively federal program. In sum, Congress has deliberately occupied the field of physician reimbursement, payment, and charges with respect to the Medicare program, and the Ohio statutory scheme is therefore preempted by the Medicare Act and violative of the Supremacy Clause of the United States Constitution. The United States Court of Appeals for the Sixth Circuit erred in holding to the contrary.

CONCLUSION

For the reasons set forth hereinabove, a Writ of Certiorari should issue to review the Opinion and Judgment of the United States Court of Appeals for the Sixth Circuit.

Respectfully submitted,

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APPENDIX

RECOMMENDED FOR FULL TEXT PUBLICATION
PURSUANT TO SIXTH CIRCUIT RULE 24
ELECTRONIC CITATION: 1996 FED APP. 0158P (6TH CIR.)
FILE NAME: 96a158p.06

UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

No. 94-4232

WARREN J. DOWNHOUR, D.O., VIRGINIA FORNEY, RICHARD E. SHAW, WARREN D. JACOBS, NINO M. CAMARDESE, M.D., GEORGE LIERENZ, SAM GIALLOMBARDO, DON DAUGHERTY, SARA PRESLEY and HILDA RUGGLES, - - *Appellants,*

v.

PETER SOMANI, M.D., Individually and as Director of the Ohio Department of Health, - - - - - - - *Defendant-Appellee.*

Decided and Filed June 7, 1996

BEFORE: MARTIN, GUY, and RYAN, Circuit Judges.

RYAN, Circuit Judge. The plaintiffs, two health care practitioners and several of their patients, filed an action seeking declaratory and injunctive relief to restrain the defendant from enforcing OHIO REV. CODE ANN. §§ 4769.01 & 4769.02, alleging, *inter alia*, that the statutes violate the Supremacy Clause, U.S. Const. Art. VI, cl. 2, because they are preempted by the Medicare Act, 42 U.S.C. §§ 1395-1395ccc. The complaint also contended that the statutes are void for vagueness, violate due process and equal protection guarantees, and infringe upon the constitutional right to privacy. The plaintiffs appeal from the district court's grant of summary judgment in favor of the defen-

dant. Concluding that none of the plaintiffs' constitutional arguments has merit, we affirm.

I.

In 1965, Congress enacted the "Federal Health Insurance for the Aged and Disabled" program, more commonly known as Medicare. 42 U.S.C. §§ 1395-1395ccc. Part A covers those services provided by institutions such as hospitals, 42 U.S.C. §§ 1395c-1395i-4; it is not implicated by this case. Part B provides supplemental medical insurance benefits for certain health care, including physician services. 42 U.S.C. §§ 1395j-1395w-4. Benefits under Part B are administered by private insurance carriers, who in turn are supervised by the Department of Health and Human Services. 42 U.S.C. § 1395u.

Under Medicare, a physician may choose to be a "participating" physician by "accepting assignments," meaning that the physician directly bills Medicare or, more precisely, the local Medicare insurance carrier for his services. If the claim is for a reimbursable, covered service, Medicare will pay 80% of what it has determined to be its approved rate, calculated pursuant to 42 U.S.C. § 1395w-4. The Medicare beneficiary is then responsible for a copayment of the remaining 20%. A participating physician agrees to accept the resulting 100% of the approved rate as full payment, even if it is less than his actual bill. *See* 42 U.S.C. § 13951(a)(1).

In the alternative, a physician may choose not to accept assignments, which means he presents an itemized bill directly to a Medicare patient for his full charge. The patient applies in turn to Medicare, which will, as with participating physicians, reimburse 80% of its approved rate. Unlike in the case of a participating physician, however, the nonparticipating physician may then charge the patient for more than the 20% copayment, as Medicare provides that a nonparticipating physician is not prohibited from charging up to a total of 15% of the Medicare approved rate. *See* 42 U.S.C. §§ 13951(a)(1), 1395u(b)(3)(B)(i). The practice of charging the patient for

more than 20% of the Medicare-approved rate is commonly referred to as balance billing, although this is not a term used in the Medicare statute. This 115% limit was an innovation of the Omnibus Budget Reconciliation Act of 1989, which provided that, beginning January 1, 1991, non-participating physicians could balance bill only up to a "limiting charge," which, for 1991, was 25% above the Medicare-determined allowable charge; for 1992, 20 %; and for 1993 and thereafter, 15%. 42 U.S.C. § 1395w-4(g)(l)(2).

On January 14, 1993, a group of statutes relating to the ability of health care practitioners to balance bill Medicare patients became effective in Ohio. The term "health care practitioner" includes "[a) physician authorized . . . to practice medicine and surgery, osteopathic medicine and surgery, or podiatry," OHIO REV. CODE ANN. § 4769.01(C)(6) (Anderson 1994), and thus includes the plaintiff-physicians. Balance billing was originally defined as "charging or collecting an amount in excess of *the amount reimbursable under the medicare program for* medicare-covered services or supplies provided to a beneficiary of the program," OHIO REV. CODE ANN. § 4769.01(B) (Anderson 1994) (emphasis added). In the plaintiffs' view, this language imposed a requirement that a Medicare claim be filed whenever a service was performed, in order to determine what amount was "reimbursable" under Medicare. Also, as originally written, the statutes prohibited health care providers from balance billing only those Medicare patients whose family incomes were less than 600% of the poverty guidelines, but allowed balance billing of other, wealthier patients. OHIO REV. CODE ANN. § 4769.02 (Anderson 1994).

Effective November 24, 1995, however, the statute was amended, and now provides simply that "[n]o health care practitioner . . . shall balance bill for any supplies or service provided to a medicare beneficiary." OHIO REV. CODE ANN. § 4769.02 (Supp. 1995). Thus, the prohibition is no longer tied to the income level of the Medicare beneficiaries. Moreover, balance billing is now defined as "charging or collecting from a medicare beneficiary an amount in

excess of the medicare reimbursement rate for medicare-covered services or supplies provided to a medicare beneficiary. " OHIO REV. CODE ANN. § 4769.01(B) (Supp. 1995). In other words, the statute now makes plain that it only applies once a Medicare claim has been filed, and that it imposes no independent requirement of filing a claim; if no claim is filed, the Ohio prohibition on balance billing simply is not activated. The statutory prohibition is enforced through complaints filed by those Medicare beneficiaries who believe they have been overcharged and who object to it; that is, there are no independent state investigations. Violations are punished by civil penalties. *See generally* OHIO REV. CODE ANN. §§ 4769.03-. 10 (Supp. 1995).

The plaintiffs filed suit challenging only OHIO REV. CODE ANN. §§ 4769.01-.02, which define and prohibit balance billing; the plaintiffs did not challenge the enforcement provisions of the statutory scheme. The first amended complaint alleged, *inter alia*, that the statutes were impliedly preempted by Medicare. In addition, the complaint alleged that the statute's original language, then in effect, providing for differential treatment of Medicare recipients based on their income was violative of the Equal Protection Clauses and the Due Process Clauses of the Fifth and Fourteenth Amendments. The plaintiffs further contended that the statutes were void for vagueness, because of the failure to define terms such as "family income." Finally, the plaintiffs asserted that the Ohio law required them to file Medicare claims in order to determine whether a claim was "reimbursable," and that this requirement violated their constitutional right to privacy; likewise, their constitutional right to privacy was violated by an implicit requirement that patients provide their personal financial information in order to determine whether they met the 600%-of-poverty-level threshold.

On the parties' cross-motions for summary judgment, the district court granted summary judgment in favor of the defendant, dismissing all of the plaintiffs' claims. The plaintiffs then filed this timely appeal.

II.

When a district court's disposition of a case on crossmotions for summary judgment involves purely legal issues, this court's review is plenary. *Schilz* v. *City of Taylor,* 825 F.2d 944, 946 (6th Cir. 1987).

III.

A.

At the heart of the plaintiffs' appeal is their argument that the Ohio statutes in question are preempted by Medicare. There has traditionally been a presumption against federal preemption of state law. *Broyde* v. *Gotham Tower, Inc.,* 13 F.3d 994, 997 (6th Cir.) (citing *Cipollone* v. *Liggett Group, Inc.,* 505 U.S. 504 (1992)), *cert. denied,* 114 S. Ct. 2137 (1994); *see New York State Conference of Blue Cross & Blue Shield Plans* v. *Travelers Ins. Co., 115* S. Ct. 1671, 1676 (1995). There is, moreover, an additional and related judicial "assumption that the historic police powers of the States [are] not to be superseded by . . . Federal [law] unless that was the clear and manifest purpose of Congress. "' *Interstate Towing Assn, Inc.* v. *City of Cincinnati,* 6 F.3d 1154, 1161 (6th Cir. 1993) (quoting *Rice* v. *Santa Fe Elevator Corp.,* 331 U.S. 218, 230 (1947)); *see New York State Conference, 115* S. Ct. at 1676. Accordingly, if the subject matter of the state statute is one within the state's traditional powers, the party arguing federal preemption must show that preemption was the "clear and manifest purpose of Congress. " *Pacific Gas & Elec. Co.* v. *State Energy Resources Conservation & Dev. Comm'n,* 461 U.S. 190, 206 (1983).

As an initial matter, the parties disagree whether the Ohio statutes address a subject traditionally regulated by the states, thus requiring the plaintiffs to satisfy the high "clear and manifest purpose" standard. While public health care is indisputably such a traditionally regulated matter, *see New York State Conference,* 115 S. Ct. at 1676-77; *Hillsborough County* v. *Automated Medical Lab., Inc.,* 471 U.S. 707, 719 (1985), the plaintiffs suggest that the Ohio statutes regulate only medical costs, a subject that falls

outside the purview of state police power. For support, the plaintiffs point to Judge Sloviter's dissent to *Pennsylvania Medical Society* v. *Marconis,* 942 F.2d 842, 858 (3d Cir. 1991), in which the Third Circuit addressed the issues that confront us here and found no preemption. Judge Sloviter contended that while *public health* may be a matter within a state's police powers, *medical billing* is not, and thus a law banning balance billing is not entitled to any favorable presumptions. We disagree. The suggested distinction is interesting, but we think a health provider's billing practices are inextricably linked to public access to medical care—that is, public health. Regulation of public health presupposes and encompasses the regulation of the cost of medical care. The two issues are therefore really one, and are, together, within a state's police powers. Consequently, this court may not find that the Ohio statutes in question are preempted by Medicare unless, of course, it can be shown that preemption was the clear and manifest purpose of Congress.

B.

A congressional enactment may preempt state law in three possible ways. First, the federal law may contain "an express congressional command" preempting state law. *Cipollone,* 505 U.S. at 516.

Second, state law may be impliedly preempted when the state law "actually conflicts with federal law," id., either because "it is impossible to comply with both state and federal law, or [because] the state law is an obstacle to the accomplishment of the full purposes and objectives of Congress in enacting the federal legislation," *Marconis,* 942 F.2d at 848. An actual conflict analysis should be narrow and precise, "to prevent the diminution of the role Congress reserved to the States while at the same time preserving the federal role." *Northwest Cent. Pipeline Corp.* v. *State Corp. Comm'n,* 489 U.S. 493, 515 (1989).

Third, implied preemption also occurs when "federal law so thoroughly occupies a legislative field 'as to make reasonable the inference that Congress left no room for the

States to supplement it.' " *Cipollone,* 505 U.S. at 516 (citations omitted).

It is plain that Medicare contains no express preemption of state law, and the plaintiffs rely only on arguments of implied preemption.

C.

The practice of 'balance billing' was initially designed to benefit physicians who believed that the federal fee schedule did not adequately compensate them for the services they provided. *See Medical Soc'y of State of New York* v. *State Dept of Health,* 633 N.E.2d 468, 469-70 (N.Y. 1994). Over time, however, as the use of balance billing increased, along with a corresponding increase in out-of-pocket liabilities for Medicare beneficiaries, the practice has become controversial:

> Opponents contend that many beneficiaries are victimized by the process because they are unaware of the insurance options and often do not know that their physicians "balance bill" until after services have been rendered. They also contend that balance billing thwarts Medicare's goal of reducing health care costs for beneficiaries because it invariably increases the amount charged to the beneficiary personally. Because this amount is generally not covered by other types of insurance, "extra bills become out-of-pocket liabilities" of the patient.

Medical Soc'y of State of New York v. *Cuomo,* 976 F.2d 812, 814 (2d Cir. 1992) (citation omitted). In response to this mounting controversy, a number of states have considered banning the practice, and several have actually done so. Indeed, the laws banning or curtailing balance billing in three states—Massachusetts, Pennsylvania, and New York—have been challenged in federal courts on preemption grounds, and each has withstood the challenge. *Cuomo,* 976 F.2d 812 (New York law), aff'g 777 F. Supp. 1157 (S.D.N.Y. 1991); *Marcoois,* 942 F.2d 842 (Pennsylvania law), *aff'g* 755 F. Supp. 1305 (W.D. Pa. *1991); Massachusetts Medical Socy* v. *Dukakis,* 815 F.2d 790 (1st Cir.)

(Massachusetts law), *aff'g* 637 F. Supp. 684 (D. Mass. 1986), *cert. denied*, 484 U.S. 896 (1987). And not only have individual states been dismayed by the practice; Congress, too, "has repeatedly tried to discourage balance billing" through various legislative enactments. *Cuomo*, 976 F.2d at 814.

It is instructive to consider the language of the Medicare Act that the plaintiffs claim establishes the right of physicians to balance bill. The first such section provides that the Medicare insurance carrier

> will take such action as may be necessary to assure that, where payment under this part for a service is on a charge basis, such charge will be reasonable and not higher than the charge applicable, for a comparable service and under comparable circumstances, to the policyholders and subscribers of the carrier, and such payment will . . . be made—
>
> (i) *on the basis of an itemized bill;* or
>
> (ii) on the basis of an assignment . . . .

42 U.S.C. § 1395u(b)(3)(B) (emphasis added). According to the plaintiffs, the "itemized bill" language reflects Congress's intention to allow balance billing. Likewise, they argue, since Congress has made plain throughout section 1395u that physicians may "voluntarily" elect to become participating physicians, e.g., *4* U.S.C. ˇ 1395u(h), it follows that Congress intended not to require any physician to forego balance billing, since balance billing is the hallmark of the nonparticipating physician designation. In further support of their argument, the plaintiffs refer to the provision of the Act establishing the 115% limiting charge:

> In the cases of a nonparticipating physician . . .
>
> [n]o person may bill or collect an actual charge for the service in excess of the limiting charge . . . .
>
> . . . .
>
> For physicians' services furnished in a year after 1992, the "limiting charge" shall be 115 percent of the recognized payment amount under this part for nonparticipating physicians . . . .

42 U.S.C. § 1395w-4(g)(1)(A)(i), (2)(C). The plaintiffs suggest that by forbidding balance billing beyond 1 15 % of the Medicare-approved rate, Congress has created an affirmative entitlement for physicians to balance bill up to that amount.

We examine now, more closely, the plaintiffs' two implied preemption arguments.

(1) Actual Conflict

The plaintiffs' conclusion that Congress has created an inviolable right to balance bill that the states cannot destroy is based upon their argument that an option to balance bill is necessary to effectuate congressional purposes of maintaining a delicate balance between the competing objectives of providing beneficiaries with medical services they can afford and allowing access to physicians who charge higher fees. That argument has been made, and rejected, on several occasions in other courts. For example, in an opinion later affirmed by the Third Circuit, a district court in the Western District of Pennsylvania explained as follows:

> Showing a Congressional design to strike a particular balance . . . is not sufficient to shut states out of the process. The *[plaintiffs] must show a need or an intent that the particular balance of cost and access be nationally uniform.* Whether it is wise to stop the federal government from closing all "safety valves" throughout the nation, is of course, an entirely different question from whether it is wise to prevent states from closing one safety valve where it would serve the local interest.

Pennsylvania Medical Soc'y v. *Marconis,* 755 F. Supp. at 1312 (emphasis added). As the First Circuit observed in *Dukakis,* there is no particular "theoretical or logical" reason for national uniformity in this context; there is no uniquely federal interest in maintaining balance billing, and there is no concern, as there might be with, for example, transportation, that piecemeal state regulation will result in an unwieldy system. *See Dukakis,* 815 F.2d at

794-95. On the contrary, as the *Dukakis* court noted, there are compelling reasons for leaving the decision of whether to allow balance billing in the hands of the states:

> After all, a state is ordinarily as concerned as the federal government to see that its elderly citizens enjoy medical care. A state would not normally wish to impose a ban that would hurt those citizens more than it helped them. Indeed, a state would likely be *more* cautious than the federal government, thinking twice before imposing such a ban, for a single state's ban on balance billing risks losing doctors to other states, while a federal ban does not. Moreover, to the extent that relevant economic conditions vary from state to state, an individual state may better be able to strike the balance between "affordability" and "access" in a way that best serves its older citizens.

Id. at 795; *see also Marconis*, 942 F.2d at 852-53.

As we have noted, a state law may "actually conflict" with a federal law either because it is impossible to comply with both, or because "the state law is an obstacle to the accomplishment of the full purposes and objectives of Congress in enacting the federal legislation." *Marconis*, 942 F.2d at 848. Because it is, obviously, possible to comply with both the federal and state law at issue here, the sole question is whether Ohio's law is an obstacle to Congress's objectives in enacting Medicare.

Part of the basis for the plaintiffs' theory that Congress has granted a "right' to balance bill that Ohio cannot deny is the argument that the Medicare Act, in providing that "[n]o person may bill or collect" more than 115% of the Medicare-allowed amount, has established a "right" to "bill or collect" up to that amount. We think not. Congress has not affirmatively stated that a health care practitioner is entitled to collect up to 1 15 %, simply that he is forbidden from collecting more. That statement is certainly not equivalent to an express approval of charging 1 15 % even less is it a clear and manifest intention that such a "right" be preserved to the exclusion of contrary state laws. Moreover, as pointed out so well by other courts, there is no

suggestion in the statute or legislative history that there is a need for national uniformity on the issue of balance billing, and there are, indeed, many persuasive reasons to conclude that state-specific legislation is preferable. In short, the plaintiffs' suggestion that Ohio's law is impliedly preempted because of an actual conflict with the Medicare Act must fail.

(2) Occupation of the Field

The plaintiffs have argued that Medicare's extensive and complex regulation of physician fees indicates an intent to occupy the field. We note, first, that it is well-established that comprehensiveness of a statutory scheme is important in the preemption analysis only to the extent it shows a desire for exclusivity; comprehensiveness, without a concomitant congressional indication of intention to preempt, is insufficient to preclude state law. *Hillsborough County,* 471 U.S. at 717. There is no indication in Medicare's balance billing provisions of a congressional desire for exclusivity; thus, the mere fact that Medicare is long and complicated is unimportant.

Second, the plaintiffs' claim is belied by Medicare's explicit statement of a *lack* of intention to occupy the field of compensation of health providers:

> Nothing in this subchapter shall be construed to authorize any Federal officer or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided, or over the selection, tenure, or compensation of any officer or employee of any institution, agency, or person providing health services

42 U.S.C. § 1395. This statement, a fairly straightforward message by Congress conceding state sovereignty over the issue of regulation of physician fees, counsels strongly against the plaintiffs' claims. In fact, courts have described this language as an "unambiguous sentiment" presenting a serious impediment to any argument that Congress intended Medicare to occupy the balance-billing field. *See, e.g., Cuomo,* 976 F.2d at 818.

Finally, we note that Congress has long been aware of state bans on balance billing, yet it has never expressed an intent to preempt such bans. For example, Congress was unquestionably aware of state bans, and federal court decisions approving them, at the time it made extensive changes to Medicare in 1989. At that time, the Physician Payment Review Commission, an advisory body to Congress established by the Omnibus Budget Reconciliation Act of 1986, 42 U.S.C. ˜ 1395w-1, submitted a report to Congress which included an appendix listing the four states that at the time had statutes restricting balance billing (Massachusetts, Rhode Island, Connecticut, and Vermont), as well as the additional eighteen states that had considered such statutes. PPRC, 1989 Annual Report to Congress 371 *(cited in Marconis,* 942 F.2d at 850). Moreover, the PPRC Report cited the First Circuit's 1987 *Dukakis* decision, in which the Massachusetts law banning balance billing was unsuccessfully challenged on preemption grounds. At the same time, the General Accounting Office issued a forty-one page report surveying the costs and benefits of state balance billing practices, which likewise referred to the First Circuit opinion. *See* GAO, *MEDICARE: Impact of State Mandatory Assignment Programs on Beneficiaries* (September 1989) *(cited in Cuomo,* 976 F.2d at 815).

On the one hand, we should "generally [be] reluctant to draw inferences from Congress' failure to act," *Schneidewind* v. *ANI? Pipeline Co.,* 485 U.S. 293, 306 (1988), as "congressional silence provides [but] a squishy reed upon which to base congressional intent," *Cuomo,* 976 F.2d at 818. On the other, Congress's failure to explicitly preempt when it was so clearly aware of the backdrop of state regulation is more significant than the usual failure to act, a consideration that the *Marconis* court found highly persuasive:

> The appellants cannot overcome the fact that, at the time of the Medicare amendments in 1989, and since then, Congress was and has been undisputedly aware of the fact that at least four states had balance billing

> restriction statutes and that similar restrictions had been considered by some 18 states. . . . This information was included in the PPRC report submitted to Congress in 1989. But in the face of this information, Congress did not include a specific preemption provision in the 1989 amendments to Medicare, nor has it done so since. The Supreme Court in a precedent we are not free to disregard has noted that *when Congress remains silent regarding the preemptive effect of its legislation on state laws it knows to be in existence at the time of such legislation's passing, Congress has failed to evince the requisite clear and manifest purpose to supersede those state laws.* Furthermore, in this case the silence is particularly indicative of congressional intent, given the extraordinary oversight of the Medicare program as evidenced by the very existence of the PPRC with its annual reports to Congress and by the frequent amendment of the Medicare Act. Congress has simply not preempted state balance billing restrictions.

Marconis, 942 F.2d at 850 (emphasis added) (citing *California Fed. Sav. & Loan Ass'n* v. *Guerra,* 479 U.S. 272, 287-88 (1987)). Like the *Marconis* court, in the peculiar context presented here, we find the congressional silence resounding.

In sum, we find the fact that Congress elected not to place a federal ban on balance billing carries little weight as an indication that it intended to displace *state* bans, under the special circumstances of Medicare legislation. Congress has long been aware that several states have banned balance billing, and that those bans have been upheld by the courts. In such circumstances, congressional silence, and the failure to explicitly preempt, becomes much more significant than it otherwise would be. Moreover, recognizing the considerable burden the plaintiffs face in advancing their claim, we conclude that there can be no serious debate that the plaintiffs have not shown a clear and manifest congressional purpose to occupy the field of balance billing.

D.

Finally, we turn briefly to the remainder of the plaintiffs' claims, which are premised solely on language now abandoned by the statutory amendments enacted during the pendency of this appeal. We entertain considerable doubt as to whether those arguments have not been rendered moot, given that the plaintiffs are, after all, requesting only prospective injunctive relief, and given, further, that the Ohio Department of Health has issued an informational publication stating that it intends to follow the amended law in its implementation of the balance billing program. *See generally Jones* v. *Temmer,* 57 F. 3d 921 (10th Cir. 1995). At oral argument, however, the plaintiffs specifically declined to concede mootness, stating simply that the amendments had not led them to "necessarily forego" their remaining claims. Rather than address at length the complex mootness question, which has not been briefed, we will simply proceed to the merits.

As we have already described, beyond their preemption argument, the plaintiffs have contended that the Ohio statutes at issue are void for vagueness because of their failure to define various terms; that they are violative of due process and equal protection guarantees because they differentiate between groups of citizens based on income; and that they infringe upon the constitutional right to privacy both by requiring physicians to file a Medicare claim in order to determine if the particular claim was "reimbursable," and by requiring patients to provide their personal financial information in order to determine whether they meet the 600%-of-poverty-level threshold. These arguments, we conclude, are without merit.

First, the Ohio statutes, as previously written, more than adequately conveyed the applicable standard of conduct, and so were not impermissibly vague. *See, e.g., Village of Hoffman Estates* v. *Flipside, Hoffman Estates, Inc.,* 455 U.S. 489, 498 (1982); *Grayned* v. *City of Rockford,* 408 U.S. 104, 108 (1972). Next, the previously existing differentiation between groups of Medicare recipients based on

their income is a differentiation amply supported by the legitimate state interest of desiring to control medical costs for those least able to afford them. *See City of Cleburne* v. *Cleburne Living Ctr.*, 473 U.S. 432, 440 (1985). Finally, the plaintiffs' right-to-privacy arguments fail on two grounds. One, our reading of the first version of the Ohio statute discloses no requirement that a Medicare claim be filed; any such requirement is imposed by the Medicare Act itself, not by the Ohio balance-billing ban. Two, the constitutional right to privacy does not extend to protect the plaintiffs' desire not to disclose their private financial information under these circumstances. *See, e.g., Jarvis* v. Wellman, 52 F.3d 125, 126 (6th Cir. 1995); *cf. Whalen* v. *Roe*, 429 U.S. 589, 602 (1977).

IV.

AFFIRMED.

UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

No. 94-4232

WARREN J. DOWNHOUR, D.O., VIRGINIA FORNEY, RICHARD E. SHAW, WARREN D. JACOBS, NINO M. CAMARDESE, M.D., GEORGE LIERENZ, SAM GIALLOMBARDO, DON DAUGHERTY, SARA PRESLEY and HILDA RUGGLES, - - *Appellants,*

v.

PETER SOMANI, M.D., Individually and as Director of the Ohio Department of Health, - - - - - - - *Defendant-Appellee.*

JUDGMENT—Issued July 1, 1996

BEFORE: MARTIN, GUY, and RYAN, Circuit Judges.

ON APPEAL from the United States District Court for the Northern District of Ohio at Toledo.

THIS CAUSE was heard on the record from the district court and was argued by counsel.

IN CONSIDERATION WHEREOF, it is ORDERED that the judgment of the district court is AFFIRMED.

ENTEREDBY ORDER OF THE COURT
/s/ Leonard Green, Clerk
Leonard Green, Clerk

Attest:
/s/ (Illegible)
Deputy Clerk

IN THE

UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF OHIO
WESTERN DIVISION

No. 94-4232

WARREN J. DOWNHOUR, D.O., Et Al. - - - *Plaintiff*

v.

PETER SOMANI, M.D., Ph.D., Director of Health, - - - - - - - - - - *Defendant*

MEMORANDUM AND ORDER—

Filed October 7, 1994

This action is before the court on defendant's motion to dismiss pursuant to Fed. R. Civ. P. 12(b)(6), cross motions for summary judgment pursuant to Fed. R. Civ. P. 56, and plaintiffs, application for oral argument. For the reasons stated below, plaintiffs' motion for summary judgment shall be denied, defendant's motion for summary judgment shall be granted, and defendant's motion to dismiss and plaintiffs, application for oral argument shall be overruled as moot.

This action was originally filed in this court on December 6, 1993. Plaintiffs seek declaratory and injunctive relief to restrain defendant from enforcing O.R.C. §§4769.01 and 4769.02, which ban physicians from balance billing Medicare patients with family incomes lower than 6000c of the poverty guidelines. Plaintiffs allege that these sections have been preempted by the Medicare Act, 42 U.S.C. §§1395 *et seq.*, and they violate Article VI, Clause 2; Article I, Section 10; and the First, Fourth, Fifth, Ninth and Fourteenth Amendments of the United States Constitution.

Part B of Medicare provides physicians with two payment options. They can choose to "accept assignment," which means they bill Medicare directly for their services. If the Medicare carrier finds that a claim is reimbursable, Medicare pays 80% of the Medicare-defined allowed or "reasonable" charge for the claim. 42 U.S.C. §13951(a)(1). The beneficiary is responsible for a "copayment" of the remaining 20% of the allowable charge, and the physician accepts the allowed charge as full payment.

Alternatively, a physician may choose to bill the patient directly for 100% of their charge, with Medicare reimbursing the patient for 80% of the Medicare reasonable charge. According to 42 U.S.C. §§13951(a)(1) and 1395u(b)(3)(B)(i), a physician who does not accept assignment may charge the patient in excess of the Medicare allowed charge, a practice called "balance billing." These sections also limit the amount which non-participating physicians may charge Medicare beneficiaries by establishing what is commonly referred to as the "limiting charge." The limiting charge for all services after 1992 is 115% of the fee schedule amount.

There are two groups of plaintiffs in this case. The plaintiff patients are Medicare beneficiaries with a "family income', below or equal to six hundred percent (600%) of the poverty level. Each is enrolled in Part B of the Federal Medicare Program and uses one of the plaintiff doctors on an ongoing basis. The plaintiff doctors refuse to accept assignments or enter into any participation agreement with Medicare and are "non-participating" physicians within the meaning of 42 U.S.C. §1395, *et seq*.

Plaintiff patients wish to contract independently, on a case-by-case basis, to pay for certain health care services themselves without disenrolling completely from Part B of Medicare. They desire to remain enrolled in Medicare because there is no private primary health insurance coverage available for persons over age sixty-five. Plaintiff physicians want to contract outside the limitations imposed on health costs by Medicare.

These limitations on health costs began on July 18, 1984, when the "Deficit Reduction Act of 1984" froze the fees which nonparticipating physicians could charge Medicare beneficiaries. Later, the method of physician payment under Plan B changed to correspond to a fee schedule with Medicare payment rates based on the "Resource-Based Relative Value Scale" (RBRVS). 42 U.S.C. §1395w-4.

Plaintiffs challenge O.R.C. §§4769.01 and 4769.02 which prevent health care practitioners from balance billing any Medicare beneficiaries whose family income is at or below 600% of the current poverty guidelines for a family of equal size. The parties estimate that approximately 91% of Ohio's medicare beneficiaries come within this guideline. Violation of the balance billing prohibition is punishable by a $500 fine for a first offense with subsequent offenses being punishable by fines of up to $5,000.

As a preliminary matter, defendant moves to dismiss plaintiffs, claim on the basis that plaintiffs have failed to join a necessary party pursuant to Fed. R. Civ. P. 19. Defendant asserts that plaintiffs, requested relief cannot be granted without the presence of the United States Department of Health and Human Services and Nationwide Mutual Insurance Company (Ohio's medicare carrier).

Plaintiffs stipulate, however, that they are only challenging Ohio statutes and policies and that complete relief can be granted without those parties. Though a major portion of plaintiffs, argument rests on the false assumption that the Ohio statutes require them to file claims every time a service is provided, their essential challenge is to the validity of the Ohio statutes, not the Medicare system as a whole. For that reason, the United States Department of Health and Human Services and Nationwide Mutual Insurance Company are not necessary parties under Fed. R. Civ. P. 19.

Similarly, plaintiffs' claims are ripe f or review because they only challenge the Ohio statutory limit on balance billing, not the potential existence of federal requirements

to file claims after every procedure. As such, defendant's reliance on *Stewart v. Sullivan*, 816 F.Supp. 281 (D.N.J. 1992), is not well founded, because that case involved a challenge to federal requirements that prevented private contracting on a case-by-case basis. The court in *Stewart* determined that the Secretary had not stated a position on the issue of private contracting; therefore, the challenge to the alleged policy was not ripe for judicial decision. *Id.* at 290.

In contrast, plaintiffs in the present case do not challenge undefined federal requirements; they direct their attack on specific Ohio laws which carry potential sanctions for noncompliance. Because plaintiffs' complaint raises a facial attack on the constitutionality of O.R.C. §§4769.01 and 4769.02 and presents a purely legal question, now is the time to decide the issue. *See Whitney* v. *Heckler*, 780 F.2d 963, 969 (11th Cir. 1986) (an "issue is ripe for judicial review when the challenging party is placed in the dilemma of incurring the disadvantages of complying or risking penalties for noncompliance").

In their challenge to Ohio's limitation on balance billing, plaintiffs first argue that the Medicare Act, 42 U.S.C. §§1395, *et sect.*, preempts O.R.C. ¯4769.01 and 4769.02, because the Medicare legislative scheme is so pervasive as to imply preemption-and the Medicare legislation conflicts with the Ohio statutes.

The Ohio statutes are preempted only if Congress intended to do *so. California Fed. Sav. & Loan Ass'n.* v. *Guerra*, U.S. ___, 107 S.Ct. 683 (1987). For plaintiffs to prevail on their implied preemption argument, I must conclude that Congress intended to preempt the field of Medicare health cost regulation. Plaintiffs can, however, only show that balance billing has been an option under medicare since its inception in 1965, and Congress has consistently refused to ban balance billing. These aspects of the statutory scheme indicate quite clearly that Congress envisioned, and continues to envision, a role for state regulation in this area.

Every court addressing the question has held that Congress did not intend to preempt state action limiting balance billing under the Medicare Act. In *Massachusetts Medical Soc.* v. *Dukakis*, 815 F.2d 790 (1st Cir. 1987), the court, noting that the field of medical fee regulation tradition is a state concern, held that Congress did not intend to create a right to balance bill. Beginning with the presumption that Congress did not intend to displace state law, Id. at 793, the court closely reviewed the same Congressional record on which plaintiffs rely and determined that Congress intended at most to allow the status quo to continue rather than imposing a federal ban. The court in *Massachusetts Medical* Soc., thus, upheld the state's ban on all balance billing.

The court in *Pennsylvania Medical Soc.* v. *Marconis*, 942 F.2d 842 (3rd Cir. 1991), approving a similar state ban on balance billing, found that *Massachusetts Medical* Soc. strongly supported an inference that Congress did not intend preemption, because Congress was aware of that case and the existence of state laws restricting balance billing, yet remained silent as to preemption in subsequent Medicare amendments. Similarly, the court in *Medical Soc. of N.Y.* v. Cuomo, 777 F.Supp. 1157 (S.D.N.Y. 1991), upheld a statute limiting balance billing to amounts less than that allowed by Medicare.

Plaintiffs further contend that Ohio's limits on balance billing are impliedly preempted because they directly interfere with the Medicare program's policy goals of assuring access to medical care and the ability of Medicare patients to choose their physician. Plaintiffs argue that forbidding the patient from providing a federally-recognized financial incentive for that physician to treat the patient limits patients, abilities to meet those goals.

Conflict preemption requires a state law to be struck down if: (1) it is impossible to comply with both the federal and state statutes, or (2) the state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Guerra, supra*, 479 U.S.

at 281. Because plaintiffs can comply with both the Ohio and federal statutes, the first prong of conflict analysis is not applicable.

The second prong of conflict analysis also does not apply to plaintiffs, argument. In the Medicare Act and its subsequent revisions,, Congress has sought to balance affordability with access to medical care, "but there is no evidence that the design of Congress encompassed national uniformity . . . Congress left room for the states to regulate physician costs." *Medical Soc. of N. Y., supra,* 777 F.Supp. at 1164. Because O.R.C. §§ 4769.01 and 4769.02 do not "stand as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," I reject plaintiffs' implied preemption challenge.

I further reject plaintiffs, contention that the Health Care Financing Administration (HCFA) has exclusive oversight of physician payment reform under Medicare. As noted by the great weight of authority, the regulation of public health and the cost of medical care is a matter traditionally within the police powers of the state. *Hillsborough County* v. *Automated Medical Laboratories, Inc.,* 471 U.S. 707, 719 (1985) ("the regulation of health and safety matters is primarily, and historically, a matter of local concern,"); *Massachusetts Medical* Soc., *supra,* 815 F.2d at '91 (interpreting the first section of the Medicare Act as intending to minimize federal intrusion into the field of fee regulation of medical services for the elderly). Because Congress did not intend to preempt the regulation of physician payment reform, as already discussed, the HCFA could not have exclusive oversight over a field which has been traditionally within the powers of the state.

Plaintiffs fail to distinguish or otherwise overcome the persuasive power of these authorities. Though none is a Sixth Circuit decision, each is persuasive because all directly concern challenges to state limitations on physicians, ability to balance bill. Despite plaintiffs, conclusory assertion to the contrary, no different presumption governs the present case. Merely making a federal regulatory program

vast does not automatically make it preemptive, and HCFA does not have exclusive jurisdiction over physician payment issues. Nor does plaintiffs, "Hobson's choice" make the Medicare Act preemptive, because the physicians, potential risk of punishment does not affect the only consideration, Congressional intent, in preemption analysis.

Plaintiffs correctly assert that none of the foregoing authority addresses the issue of whether Medicare patients have a right to contract privately for health care services on a case-by-case basis. Whether patients have that opportunity does not change the final conclusion that Congress did not intend Medicare to preempt state control over physician payment and access to health care. Later Congressional history supports that conclusion. In the seven years since *Massachusetts Medical* Soc., Congress has not taken clear and unmistakable steps to demonstrate an intent to preempt all issues dealing with physician payment through Medicare. "Surely if Congress intended to occupy the field it would have expelled the state intruders." *Pennsylvania Medical Soc., supra*, 942 F.2d at 851.

Plaintiffs, second argument invokes a tortured exegesis of the Medicare Act that fails,' however, to prove that they are entitled to contract privately for health care services without filing a Medicare claim. This argument depends on the fact that Medicare does not reimburse physicians or patients for all medical services or supplies provided to a patient. Plaintiffs allege that they often desire physicians' services which are not reimbursable; thus, they should be able to contract privately for health care services without submitting a claim to the Medicare carrier and without disenrolling from Medicare. They assert that this scheme is contrary to O.R.C. §4769.01, which, in their view, requires a claim to be submitted to the Medicare carrier whenever a service is rendered to determine whether the service is reimbursable.

Sections 4769.01 and 4769.02 do not, however, require filing of a claim every time a service is rendered. Instead, that chapter merely establishes a system by which the

Department of Health can hear and investigate complaints alleging violations of O.R.C. §4769.02. Contrary to plaintiffs, allegations, there is no "complex income-verification process" or "massive bureaucratic hurdle which must be jumped before health care services can be provided to a Medicare beneficiary." These sections do not conflict with plaintiffs, desire not to file Medicare forms for every procedure. These provisions simply guarantee a patient's right not to be billed for procedures he or she cannot afford.

Plaintiffs claim the Ohio statute has a chilling effect on patients claiming Medicare benefits, because claims are sometimes denied for lack of "reasonableness" or "necessity." Because the Ohio statutes limit physicians to collecting amounts "reimbursable" under the medicare program "for Medicare-covered services or supplies provided to a beneficiary of the program", plaintiffs assert that the law is violated every time the Medicare carrier denies a claim after payment has already been collected from the patient. Plaintiffs contend that this scheme discourages physicians from providing services to Medicare patients, contrary to Congressional intent when it adopted the Medicare program.

Plaintiffs fail to acknowledge that once a claim has been denied for Medicare coverage, the physicians and patients are no longer within the ambit of O.R.C. §4769.01. This means that the plaintiff physicians can collect fees if the procedure is not "reimbursable" under Medicare. If the service is unnecessary or unreasonable, Ohio cannot impose a sanction against the doctor under O.R.C. §§4769, et *sea.;* thus, there is no chilling effect on patients claiming Medicare benefits.

Patient plaintiffs also contend that requiring them to disclose their income tax returns while filing a Medicare claim for the purpose of determining reimbursability violates the right to privacy guaranteed by the First, Fourth, Fifth and Ninth Amendments to the United States Constitution. Plaintiffs argue that the requirement infringes on their liberty interest in protecting the privacy of their medi-

cal records and medical treatment choices, especially when the State of Ohio does not have any monetary interest in the matter because the plaintiffs wish to pay for the procedures themselves.

Again, plaintiffs, argument assumes a requirement to file claims after every procedure which does not exist in O.R.C. §§4769, *et seg.*. The statutory scheme requires disclosure of a patient's financial records only after the patient has filed a complaint. There is not any unconsented invasion of plaintiffs, medical or financial records on a claim-by-claim basis, and their privacy interests are not violated by the Ohio statutory scheme. Furthermore, as noted earlier, states traditionally have regulated medical fees, regardless of whether the state is paying the bill.

Plaintiffs further assert that the Ohio statutes violate their due process and equal protection rights because the requirement to submit a claim for a determination of reimbursability is arbitrary and irrational. This argument asserts that plaintiffs should not have to submit to a governmental bureaucracy simply because they turned sixty-five, nor should they be denied access to their physician of choice merely because they do not meet an allegedly arbitrary income classification.

The United States Supreme Court stated in *City of Cleburne* v. *Cleburne Living Center, Inc.*, 473 U.S. 432, 440 (1985), that:

> The general rule is that legislation is presumed to be valid and will be sustained if the classification drawn by the statute is rationally related to a legitimate state interest. When social or economic legislation is at issue, the Equal Protection Clause allows the states wide latitude and the Constitution presumes that even improvident decisions will eventually be rectified by the democratic process.

Plaintiffs carry an extremely heavy burden, and the statute will fail rational basis review only if the classification rests on grounds wholly irrelevant to the achievement of the State's objective. *Borman's, Inc.* v. *Michigan Prop). & Cas. Guar. Ass'n.*, 925 F.2d 160, 162 (1991) (cites omitted).

Setting aside plaintiffs, incorrect assumption that Ohio always requires a claim for reimbursement, the Ohio statute does not violate due process and equal protection rights. First, Chapter 4769 contains no age classifications; those are a product of federal, not Ohio law. Second, the creation of two groups of beneficiaries, those with a family income greater than 600% of the poverty guideline and those with lower incomes, is supported by a rational state interest, namely the state's desire to control medical costs for those least able to afford them.

While the choice of "600% of the poverty guideline" might be an imperfect measure of a family's ability to pay medical bills above Medicare's limiting charge, the test for constitutional purposes is not whether-the legislative scheme is imperfect , but whether it is wholly irrational. Id., at 163 *(citing Pennell v. City of San Jose*, 485 U.S. 1, 13-14 (1988)). Plaintiffs fail to present any evidence that this rough mechanism is irrational, so it must be upheld under rational basis review.

Plaintiffs also contend that O.R.C. §4769.02 is unconstitutionally vague. They assert the statute does not meet the substantive due process standard because it requires persons of ordinary intelligence to guess at its meaning and differ as to its application. They argue that "family income", is undefined and that this is fatal to the Ohio legislative scheme.[1]

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[1]Plaintiffs also argue that the Ohio statute somehow requires physician not to charge anything for certain procedures due t concern that the procedure might be deemed "not reimbursable pursuant to federal requirements. As explained above, this argument is without merit, because procedures which are "not reimbursable under Medicare are not covered by the Ohio balance billing statute There are no adverse consequences for the physicians (except that they must return their fees pursuant to federal law) under Chapter 4769 if the procedure is "not reimbursable."

For a statute to be void for vagueness, a court must determine that the statute does not give "the person of ordinary intelligence a reasonable opportunity to know what is prohibited, so that he may act accordingly." *Grayned* v. *City of Rockford*, 408 U.S. 104, 108 (1972). When the statute is civil rather than criminal, the threshold required to make a finding of "vagueness" is even more stringent. *Hoffman Estates* v. *Flipside, Hoffman Estates, Inc.*, 455 U.S. 489, 499 (1982). To invalidate a civil statute, a reviewing court must find that "no standard of conduct is specified at all." *Coates* v. *Cincinnati*, 402 U.S. 611, 614 (1971).

Plaintiffs, contention that O.R.C. ¨4769.01 and 4769.02 are void for vagueness is without merit, because a standard of conduct is specified. Namely, if physicians wish to balance bill, they must take it upon themselves to determine their patients, income and the physicians must avail themselves of public information to determine the "poverty guideline." This information is published in the Federal Register every February, and it is also available in documents sent to anyone on request. Even the Ohio State Medical Association has provided information about balance billing guidelines in its newsletter. (Nargang Dep., Ex. E).

Also pending is plaintiffs, application for oral argument. In light of the foregoing, that motion shall be dismissed as moot.

For the reasons stated above, it is

ORDERED THAT defendant's motion for summary judgment be and the same hereby is granted, and it is

FURTHER ORDERED THAT plaintiffs, motion for summary judgment be and the same hereby is denied, and it is

FURTHER ORDERED THAT all other pending motions be overruled as moot.

So ordered.

/s/ James G. Carr
United States District Judge

NORTHERN DISTRICT OF OHIO
WESTERN DIVISION

UNITED STATES DISTRICT COURT

Case No. 3:93CV7704

WARREN J. DOWNHOUR, D.O., Et Al., - - - *Plaintiffs,,*

v.

PETER SOMANI, M.D., - - - - - - - *Defendant.*

JUDGMENT IN A CIVIL CASE

—Filed October 18, 1994

☐ **Jury Verdict.** This action came before the Court for a trial by jury. The issues have been tried and the jury has rendered its verdict.

☒ **Decision by Court.** This action came to hearing before the Court. The issues have been heard and a decision has been rendered.

IT IS ORDERED AND ADJUDGED that defendants' motion for summary judgment is hereby *granted;* and plaintiff's motion for summary judgment is denied; and all other pending motions are overruled as moot.

Case closed.

It Is So Ordered.

/s/ (Illegible)
U.S. District Judge

Date: October 18, 1994

Geri M. Smith
Clerk

By: /s/ Cynthia (Illegible)
Deputy Clerk